

### **REMARKS**

This Amendment is being filed in response to the Office Action mailed on May 6, 2004, and is timely filed. Claims 1-64 are currently pending in this application and stand rejected. Applicants respectfully request reconsideration and allowance of the pending claims in the present application in view of the amendments and remarks below.

Applicants acknowledge the Examiner has withdrawn his rejection based on Double Patenting.

The Examiner has rejected all claims 1-64 under 35 U.S.C. 103(a) as being unpatentable in view of *Stainmesse* in view of *Cima* (U.S. Publication No. 2002/0048610 A1). *Cima* was published on April 21, 2002 and claims priority to a provisional application filed on January 7, 2000. Thus, *Cima* is prior art under 35 U.S.C. 102(e). Applicants have attached a Declaration under 37 C.F.R. 1.131 of a joint inventor Mark Doty averring that he conceived the claimed invention prior to January 7, 2000, and worked on this matter diligently thereafter. Accordingly, *Cima* should be excluded as a reference by virtue of this Declaration. Further, the Examiner cannot rely on a combination of *Stainmesse* and *Cima*, and, therefore, Applicants respectfully request a withdrawal of this rejection.

### **Conclusion**

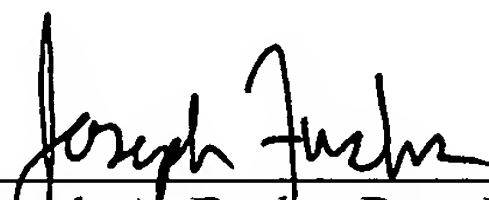
In view of the foregoing, Applicants submit the claims are in condition for allowance and respectfully request an early notice of the same.

Respectfully submitted,

EVEREST INTELLECTUAL PROPERTY LAW GROUP

Date: August 4, 2004

BY

  
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Joseph A. Fuchs, Reg. No. 34,604  
P.O. Box 708  
Northbrook, IL 60065  
Phone: (847) 272-3400



Atty Dkt. No. IFT-5657A-1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application Of: )  
Werling et al. )  
For: METHOD FOR PREPARING )  
SUBMICRON SUSPENSIONS )  
WITH POLYMORPH CONTROL )  
Serial No.: 10/035,821 )  
Filed: October 19, 2001 )  
Examiner: Simon J. Oh )  
Art Unit: 1615 )  
Conf. No. 2470 )

CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Office with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 4, 2004.

  
Judith L. Goldberg

DECLARATION

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22202

Sir:

I, Mark Doty aver as follows:

1. I am over the age of twenty-one years and make these statements from my own personal knowledge.
2. I have received a Bachelors Degree in Chemical Engineering from the University of Minnesota in 1987 and a Doctor of Philosophy Degree in Chemistry from Iowa State University in 1995.
3. I have been employed by Baxter since 1995 and currently hold the position of Associate Director of Research.
4. I am a joint inventor on U.S. Patent Application Serial No. 10/035,821.
5. I have reviewed the claims of this application and I believe that the claimed invention was conceived prior to January 7, 2000 and I have diligently worked on this project since this time.
6. As evidence of this I have attached laboratory notebook pages with dates redacted. The laboratory notebook pages are not necessarily the earliest date of conception of

the claimed invention and do not represent the results of an exhaustive search for evidence of the earliest date of conception or reduction to practice.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, I acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issuing thereon.

Date: August 4, 2004

BY   
Mark J. Doty



BOOK NO. 20744 - 39

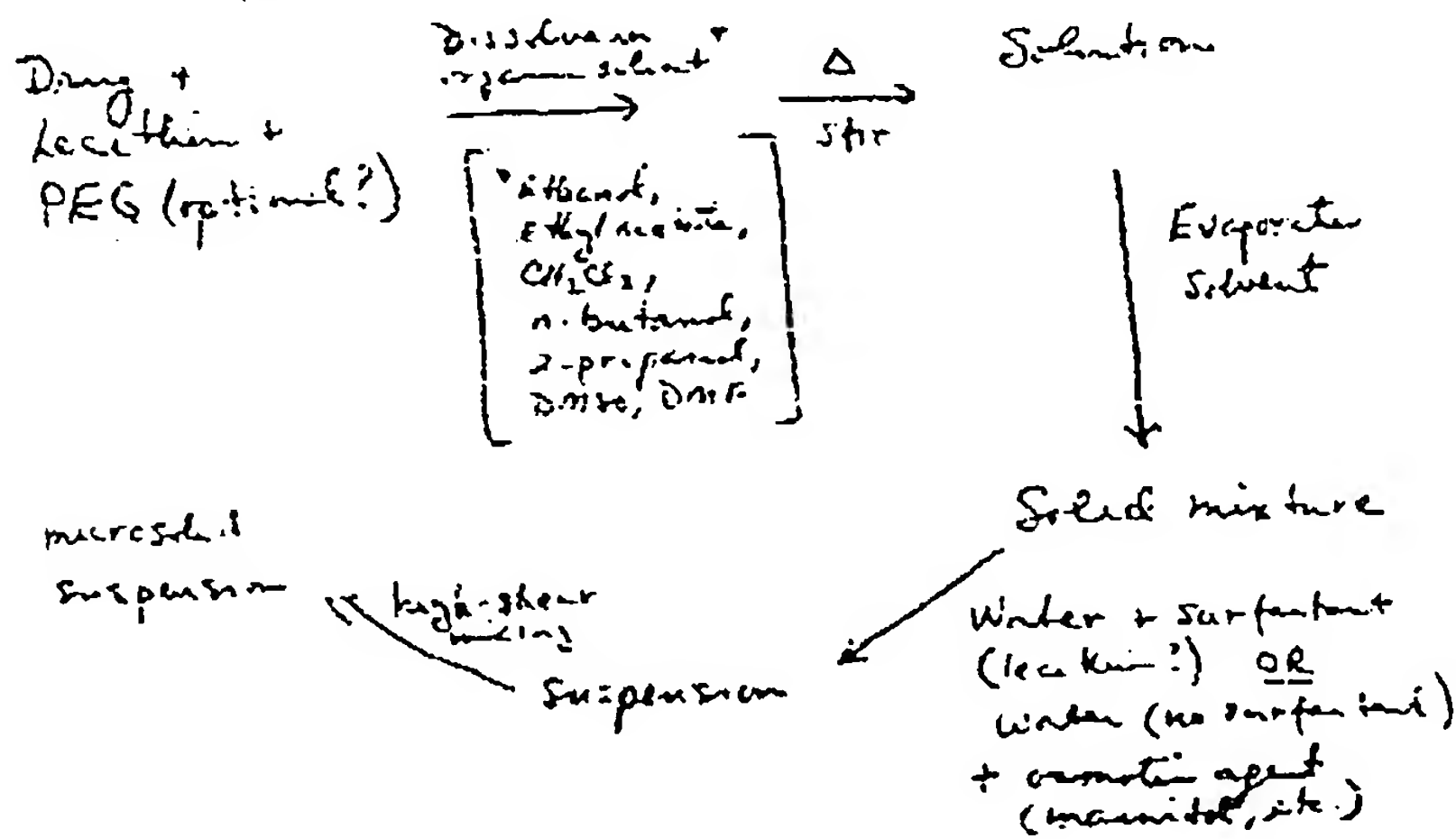
Solid Dispersion of Prednisolone - Lecithin

FPM 170

Notebook

Purpose:

Test the hypothesis that one can make microcrystals (or minimize particle size in a micro-suspension) by first preparing a solid dispersion of the drug in a matrix such as PEG (polyethylene glycol) and/or phosphatidylglycerol <sup>3/11/99</sup> phosphatidyl alcohol (or lecithin). The solid is then resuspended in an aqueous solvent (water + surfactant). Hopefully! high shear mixing (stirring; ? homogenization?) will cause breakdown of the solid to form microcrystals (or microcrystalline amorphous solid drug) in suspension.

General procedure:

I will first attempt to prepare a 1% prednisolone suspension using a 5% (w/w) solid dispersion of drug + lecithin (as egg phosphatides). This solid will be <sup>3/11/99</sup> dispersed in an aqueous medium (water + mannitol). Call this formulation FORMULATION I.

J. S. Kijne

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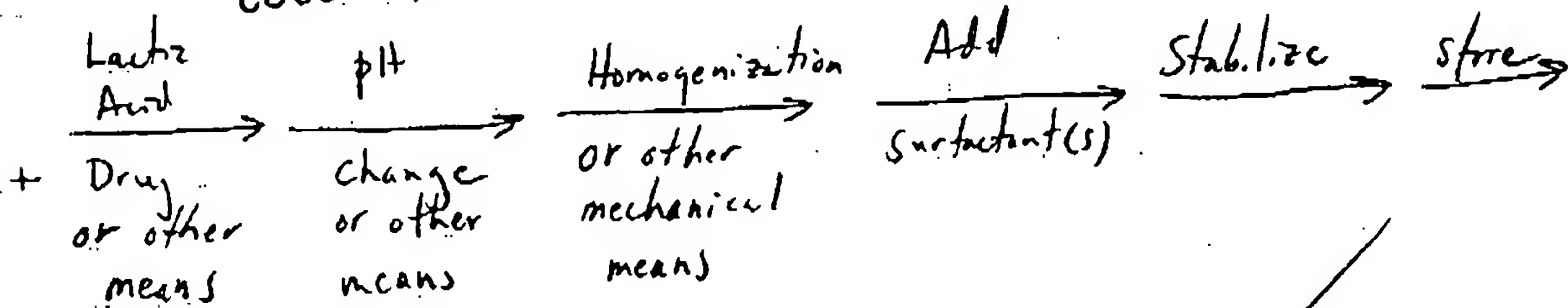
BOOK NO. 20813 - 60

TITLE pH-precipitation of Lactz Acid Prior to Homogenization

From Page No. 1 PCA or Project 1

Pro. No. 1

Purpose: Note an idea. Use pH-induced <sup>micro</sup>precipitation of Intracmarole prior to homogenization to reduce particle size. Use lactic acid to solubilize the drug. (see Chem. Pharm. Bull, 46(8), 1333-1334 (1998)).



SIGNATURE

*Muh J*

DATE

REVIEW

*[Signature]*

DATE

To Page No. 1

DRYTEX . . . . .

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